GlaxoSmithKline

Statement of GlaxoSmithKline Opposing House Bills 4316, 4317 and 4318
March 18, 2009

GlaxoSmithKline ("GSK") appreciates this opportunity to submit this statement on House Bill 4316, House Bill 4317, and House Bill 4318. GSK is a world-leading, research-based pharmaceutical and vaccine company with a mission to improve the quality of human life by enabling people to do more, feel better and live longer.

GSK opposes the enactment of this legislation, which risks undermining public health by taking important public health decisions out of the hands of FDA experts and encouraging the litigation-driven use of speculative and scientifically unsupported drug safety warnings.

House Bill 4316 seeks to repeal Michigan's existing defense to product liability lawsuits for prescription drug manufacturers ("Section 2946(5)"), which applies where a drug was approved for safety and efficacy by the U.S. Food & Drug Administration ("FDA") and the drug and its labeling were in compliance with the FDA approval at the time the drug left the manufacturer's control.

House Bill 4317 would retroactively allow pharmaceutical product liability lawsuits for claims that could have been brought as early as January 2, 1996, absent the statutory bar.

House Bill 4318 seeks to amend Michigan's consumer protection law to expressly include pharmaceuticals and to add a new cause of action against manufacturers for "failing to accurately represent the risks involved" in the intended use of a prescription or over-the-counter drug or medication, herbal product, dietary supplement, or botanical extract.

Michigan's FDA defenses must be preserved

The United States Supreme Court recently ruled in *Wyeth v. Levine* that a federal legal doctrine did not require dismissal of certain state failure to warn lawsuits involving FDA-approved drug labeling. The *Levine* ruling did not affect individual states' ability to decide the important public policy question of how much deference their tort law should give to the fact that a product was approved by the FDA.

Michigan's statutory FDA defense to product liability cases reflects the legislative determination "that a drug manufacturer or seller that has properly obtained FDA approval of a drug product has acted sufficiently prudently so that no tort liability may lie." *Taylor v. SmithKlineBeecham Corp.*, 468 Mich. 1, 8, 658 N.W.2d 127, 131 (Mich. 2003). In enacting this statute, the Michigan Legislation chose to limit the adverse financial impact of unwarranted and excessive litigation on Michigan consumers and physicians, pharmacists, and others in the health care industry; the state's court system; and companies that develop and manufacturer prescription drugs.

This is a sensible approach. Under federal law, the FDA is the expert government agency charged with the authority to review and approve prescription drugs, including

Trial lawyers often include doctors in state court drug product liability lawsuits. Abolishing the FDA defense and encouraging increased pharmaceutical litigation will put Michigan's physicians at risk of increased litigation and higher insurance premiums as a result of being pulled into cases against drug companies. Doctors also could face additional medical malpractice lawsuits and higher premiums for failing to choose to give a given warning from drug labeling crowded with liability-driven warnings.

Other potential effects of abolishing Michigan's FDA defense include increasing drug prices and decreasing innovation and availability of medicines. Bringing a new drug to market is risky and expensive; unnecessary and unpredictable lawsuits undermine the significant up-front investment required for development of potentially promising new medicines. State tort suits challenging the warnings on FDA-approved drug labeling also eliminate potentially beneficial uses and methods of delivery of drugs, leaving doctors with fewer options for treating patients.

The same public policy reasons support rejecting the proposed amendments to the consumer protection act to allow lawsuits under the act for failing to adequately represent the risks of pharmaceutical products. As the Michigan Legislature recognized when it enacted the FDA defense in 1995, the adversary system of litigation is not designed to regulate prescription drugs in the interest of the public health.

Moreover, the retroactivity imposition of wide-ranging liability for past lawful conduct creates concerns under both the United States and Michigan Constitutions. Basic notions of fairness dictate that people should have the opportunity to know what the law is and to conform their conduct to fall within the law.